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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/457,771 | 12/09/1999 | R. MARTIN EMANUELE | 19720-0624 | 8054 |

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| EXAMINER |
|---|
| SCHNIZER, RICHARD A |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1635 | |

DATE MAILED: 01/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/457,771 | Emanuele |
| **Examiner** | **Art Unit** |
| Richard Schnizer | 1635 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Oct 30, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1-4, 6-12, and 14-16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4, 6-12, and 14-16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

1. An amendment and a supplementary amendment were received and entered as Paper Nos. 18 and 20 on 8/12/02 and 10/30/02, respectively. Terminal disclaimers for US Patents 5,674,911 and 5,811,088 were received and entered as Paper No. 21 on 10/30/02.

Claims 1-4, 6-12, and 14-16 are pending and under consideration in this Office Action.

This Action contains new grounds of rejection and is NON-FINAL.

### *Compliance with Sequence Rules*

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s). This application clearly fails to comply with the requirements of 37 C.F.R.1.821-1.825. Applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). **At page 21, line 30 the specification discloses an oligonucleotide that is longer than 10 bases in length but which is not identified by a SEQ ID NO, and Applicant has not provided a Sequence Listing in either a computer readable form or on paper.**

Applicant must provide:

An initial computer readable form (CRF) copy of the "Sequence Listing".

An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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Technical Assistance.....703-287-0200

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***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-12, and 14-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, and 9 of U.S. Patent No. 5,567,859. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Instant claims 1, 6-9, and 14-16 are drawn to polyoxyethylene (POE)/polyoxypropylene (POP) copolymers with the following organization: POE-POP-POE, wherein the molecular weight of the POP portion is between about 750 and 15000 D, and the percentage of POE is between about 1 and 50% by weight. Claims 2 and 10 limit the range of POP molecular weight to 2250-15000 D, and the range of POE to 5-20%. Claims 3 and 11 limit the range of POP molecular weight to 3250-15000 D, and the range of POE to 5-20%. Claims 4 and 12 are limited to one of two a specific copolymers, i.e. CRL-8131 or CRL-8142.

Claims 1, 5, and 9 of '859 are drawn to polyoxyethylene(POE)/polyoxypropylene(POP) copolymers with the following organization: POE-POP-POE, wherein the molecular weight of the POP portion is between about 1200 and 15000 D, and the percentage of POE is between about 1 and 50% by weight, thereby overlapping the instantly claimed ranges. As an example of a copolymer of the invention claimed in '859, the specification sets forth CRL-8132 (see e.g. column 9, lines 2-6), the same copolymer recited by instant claims 4 and 12. While the specification of an issued patent generally cannot be used as prior art to support a double patenting rejection, the courts have found that the portion of a patent disclosure which supports the patent claim may be considered when determining double patenting. "[T]his use of the disclosure is not in contrainvention of the cases forbidding its use as prior art, nor is it applying a patent as a reference under 35 USC 103, since only the disclosure of the invention claimed in the patent may be considered." See In re Vogel 422 F.2d 438, 441-42, 164 USPQ 619 (CCPA 1970), and MPEP 804 (II)(B)(1). In this case the disclosure of '859 explicitly supports the copolymer recited in claims 4 and 12, thus the claims of' '859 are clearly intended to embrace the subject matter of instant claims 4 and 12. Because the claims of '859 are drawn to compositions "comprising" copolymers of the recited characteristics, it is proper to look to the specification in order to determine what else is fairly suggested to be included in the invention, i.e. to examine the portions of the disclosure of '859 which support its claims. The specification of '859 also teaches that the compositions may comprise 2%Tween 80 and 1% ethanol, which is in the range required by instant claims 7 and 15 (see e.g. column 9, lines 2-6), and that the copolymers can be used in

an admixture with a compound capable of altering gene expression and/or protein translation, such as an antisense oligonucleotide, a triplex DNA compound, or a ribozyme (see column 2, lines 1-6). The compositions are intended to be used for the delivery of nucleic acids to animals, as required by instant claims 9-12 and 14-16 (see e.g. column 1, lines 63-67), so it would have been obvious to use them for this purpose.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

### *Enablement*

4. Claims 1-4, 6-12, and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a methods and compositions for protecting a rodent from herpes simplex virus infection by intramuscular administration of a composition comprising an expression vector encoding HSV gB or gD genes, does not reasonably provide enablement for compositions and methods that depend on the function of nucleic acids to elicit treatment, and are intended to be used for the treatment of any and all animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

*Nature of the Invention*

5. Claims 1-4 and 6-8 are drawn to compositions for treating an animal, comprising one or more genes oligonucleotides antisense nucleic acids, triplex DNA compounds or ribozymes admixed with a polyethylene oxide (POE)/polypropylene oxide (POP) block copolymer in which POE blocks flank a central POP block. Claims 9-12, and 14-16 are drawn to methods of delivering a compound for altering gene activity to an animal, wherein the method comprises administering one of the compositions disclosed in claims 1-4 and 6-8. The specification discloses no purpose for delivery of nucleic acids in vivo other than therapy or immunization.

*Breadth of the Claims*

6. The claims are not limited in terms of the diseases or disorders which can be treated, or the disease against which immunization is therapeutic, or the range of animals in which treatment may be effected.

*Background*

7. Prior to the time of the invention it was known in the art that POE-POP-POE copolymers with the characteristics required by the instant claims could be used to deliver non-nucleic acid therapeutic molecules in vivo. See art rejections under 35 USC 102. For example, Allison et al (US Patent 5,376,369, issued 12/27/94) taught that POP/POE copolymers such as Pluronics L101, L121, and L122, were useful as adjuvants in the delivery of whole viruses *in vivo* as vaccines (see abstract, and column 23, lines 24-55, especially, lines 30, 31, 34, 36, 38, 46, and 55). Also Wasmoen et al (US Patent 5,656,275, issued 8/12/97) taught that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses in vivo (see column 3 line 66 to column 4,

line 28). Whole viruses comprise nucleic acids encoding genes, and qualify as expression vectors. However the prior art compositions and methods do not require function of the viral nucleic acids for vaccine activity, and instead activity is dependent upon protein antigens in the viruses. The state and unpredictability of the art of therapeutic use of nucleic acids in vivo at the time of the invention is discussed below.

*State of the Art and Predictability of the Art*

8. At the time the invention was made, successful implementation of gene therapy protocols was not routinely obtainable by those skilled in the art. This is reflected by two recently published reviews. Verma et al (Nature 389: 239-242, 1997) teach that "there is still no single outcome that we can point to as a success story (p. 239, col 1). The authors state further, "Thus far, the problem has been the inability to deliver genes efficiently and to obtain sustained expression" (p.239, col. 3). Anderson (Nature 392:25-30, 1998) confirms the unpredictable state of the art, stating that "there is still no conclusive evidence that a gene-therapy protocol has been successful in the treatment of human disease" (p. 25, col. 1) and concluding, "Several major deficiencies still exist including poor delivery systems, both viral and non-viral, and poor gene expression after genes are delivered" (p.30). More recently, Romano et al (2000) reviewed the general state of gene therapy, and found that the problems relating to gene delivery and expression discussed above persisted. See entire document, especially, last sentence of abstract; last sentence of column 1 on page 20 to column 2, line 6; page 21, column 1, lines 1-9 and 18-21; sentence bridging columns 1 and 2 on page 21; and first sentence of last paragraph on page 21. This idea

was echoed by Somia and Verma (2000), who noted that delivery vehicles still represented the Achilles heel of gene therapy, and that no single vector existed that had all of the attributes of an ideal gene therapy vector. See page 91, column 1, lines 5-13 of first paragraph.

9. The state of the art with respect to antisense therapies is set forth by Crook (In Basic Principles of Antisense Therapeutics, Springer-Verlag, Eds, New York, pgs. 1 and 4), who teaches that although antisense techniques have progressed rapidly, "the technology remains in its infancy", and the utility of the approach is still debatable (pg. 1, Introduction). Crook points out several factors which may influence the biological effect of an antisense oligonucleotide (AODN), including the rate of uptake of the AODN, rate of distribution within the target cell, stability within the target cell, local concentration of the oligonucleotide, and the concentration and stability of the target mRNA (pgs. 1 and 4). Furthermore, Branch (Trends in Biochem Sci 23: 45-50, 1998) teaches that selection of appropriate antisense sequences is difficult because secondary structures of mRNAs *in vivo* frequently restrict access of antisense oligonucleotides to the target sequence (page 45, col. 3. first para., page 48, last para. and page 49). Branch states, "Since accessibility cannot be predicted, rational design of antisense molecules is not possible" (page 49, col. 2, last para.).

10. The state of the art of genetic immunization was set forth by McCluskie et al (Molecular Medicine 5(5): 287-300, 1999). McCluskie considers the effects of the routes of administration of DNA vaccines on the quality of any resulting immune response, and considers the relevance of animal models to practice in humans. Pertinent to the instant case, McCluskie teaches that

"promising results in animal models have not been realized in human trials and considerable effort is now being focused at understanding this difference and developing ways of improving the efficacy of DNA vaccines." See final sentence of first paragraph on page 288, column 1. McCluskie points out that "[t]he strength and nature of immune responses in mice with DNA vaccines appear to be influenced by a number of factors [citation omitted]; however, these variables may not be of similar importance in larger animals including humans. As such, optimization methods developed in mice may not necessarily be applicable to humans." See page 288, column 2, first full paragraph. In fact, it is clear that some vaccines developed in mice do not function at all in some primates. At page 296, column 2, second full paragraph, McCluskie states that "[t]he realization that results in mice often do not predict the situation in humans also led to a large number of DNA vaccine studies in non-human primates, including Aotus monkeys, rhesus monkeys, and chimpanzees. IM injection of plasmid DNA vaccines, while highly immunogenic in mice was found to be only relatively so in chimpanzees and essentially not at all in Aotus monkeys. Furthermore, although early human studies have demonstrated the safety and potential of DNA vaccines, results obtained have not been as good as predicted from animal models. Collectively, these results indicate that no animal model may be ideal for prediction of efficacy in humans [citations omitted]."

11. McCluskie concludes "[i]n summary, mice may have limited value for choosing the best route of DNA vaccine delivery for humans. While efficacy in murine models has preceded the successful development of many human vaccines, it is probably safe to say that any vaccines that

work in a human will work in a mouse, but not necessarily *vice versa*. Therefore it is difficult to predict from mouse studies the potential of a new vaccine in humans. In fact, in those human trials that have been carried out, none of the DNA vaccines induced the strong immune responses that had been seen in mice with the same vectors. Furthermore, although non-human primate models are frequently used for development and testing of human vaccines, it is not clear how predictive they will be in the case of DNA vaccines where efficacy, by virtue of the requirement to first transfect cells and express antigens, relies on many factors other than immunological responses to the antigen. We will not know the answer to this until after greater experience has been achieved in non-human primates and human clinical trials." See paragraph bridging pages 296 and 297.

*Level of Skill of Those in the Art.*

12. From the foregoing it is clear that gene therapy, antisense therapy, and genetic immunization in humans were highly unpredictable at the time the invention was filed, immunization experiments in mice such as the working example in the instant specification were not predictive of results in larger animals, and even those of the highest level of skill in the biotechnological art could not perform these methods with routine success.

*Guidance and Examples in the Specification*

13. The specification teaches no working examples of gene or antisense therapy. A single example of the induction of an immune response in a mouse by administration of a block

copolymer and a nucleic acid encoding a viral antigen is given at page 30, lines 1-20. The claims are considered to be enabled for the scope of this example, as stated above.

*Amount of Experimentation Required to Practice the Invention*

14. In view of the state of the art of nucleic acid mediated therapies, including genetic immunization, the unpredictability associated with these methods, the failure of those of skill in the art to routinely obtain success in these methods, and the failure of the specification to address the art-recognized difficulties associated with these methods, one of skill in the art would have to perform undue experimentation in order to practice the invention commensurate in scope with the claims.

***Written Description***

15. Claims 1-4, 6-12, and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

16. Claims 1-4 and 6-8 are drawn to the genuses of genes, oligonucleotides, antisense nucleic acids, triplex DNA compounds and ribozymes that are useful to treat animals. Claims 9-12 and 14-16 are drawn to the genuses of genes, oligonucleotides, antisense nucleic acids, triplex DNA compounds and ribozymes "capable of altering nucleic acid function". As discussed above under enablement, it is clear from the specification that these compounds should be therapeutic in

nature, so the claimed genus is considered to be compounds capable of altering nucleic acid function to therapeutic effect in an animal.

17. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species has been described by complete structure, such as nucleotide sequence, next it is determined whether a representative number of species has been described by other relevant identifying characteristic. Applicant is referred to the Guidelines on Written Description published at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov).

18. At page 21, line 30, Applicant discloses by complete structure an antisense oligonucleotide corresponding to regions of the *art/trs* genes of HIV. However it is unclear as to whether this oligonucleotide can be used to therapeutic effect because the specification discloses no working example, and because the art of oligonucleotide mediated therapy is highly unpredictable as established above under enablement. So, it is unclear whether or not this oligonucleotide is a member of the claimed genus. The specification discloses by complete structure no other oligo- or polynucleotide that can be used for therapy. The specification discloses by relevant identifying characteristic, i.e. by name, two other genes purported to be useful in therapy. The specification discloses the ADA gene at pages 22 and 23, and the herpes simplex virus gB and gD genes at page 30. No other oligo-or polynucleotides are disclosed by any relevant identifying characteristic. There is no evidence of record that the ADA gene can be used to therapeutic

effect. The specification discloses no triplex DNAs or ribozymes by complete structure or relevant identifying characteristic.

19. The question now arises as to whether or not this disclosure constitutes a description of a representative number of species. The Guidelines on Written Description indicate that what constitutes a representative number of species varies inversely with the skill and knowledge in the art, and that in an unpredictable art such as gene therapy, adequate written description of a genus cannot be achieved by disclosing only one species within the genus. In this case, it is not clear that the specification has disclosed any single species that is representative of any of oligonucleotides, triplex compounds, antisense compounds or ribozymes, and has set forth only one example of a gene that can be used as a vaccine. Because the function of the claimed invention depends on the nature and activity of the nucleic acid comprised in the composition, description of nucleic acids that can be used to treat animals is critical to the invention. In view of these facts, one of skill in the art could not conclude that applicant was in possession of the claimed invention at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 1-4, 6-12, and 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4, 6-12, and 14-16 are indefinite because the metes and bounds of the word "genes" are unclear. The specification fails to define the term, and there is no single art-recognized definition. For example, the term is regularly used to refer only to a coding sequence (open reading frame), but is also regularly used to refer to a genetic unit comprising 5' and 3' noncoding sequences, and introns as well. It is unclear which definition Applicant intends, so it is unclear what are the metes and bounds of the claims.

Claim 8 is indefinite because it recites "the compound for altering gene activity" without antecedent basis.

21. Claims 14 and 15 are confusing because the purpose in the method of further including a surfactant and an alcohol is unclear. The claims fail to recite at what step the surfactant and alcohol should be added, or to what composition they should be added.

22. Claim 16 is confusing because the purpose in the method of further including an expression vector is unclear. The claims fail to recite at what step the expression vector should be added, or to what composition it should be added.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

23. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

24. Claims 1-4 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by either one of Allison et al (US Patent 5,376,369, issued 12/27/94), or Wasmoen et al (US Patent 5,656,275, issued 8/12/97).

Allison taught that Pluronics L101, L121, and L122, could be used as an adjuvant in the delivery of whole viruses in vivo as vaccines (see abstract, and column 23, lines 24-55, especially, lines 30, 31, 34, 36, 38, 46, and 55).

Wasmoen taught that Pluronic L121 could be used as an adjuvant in the delivery of whole viruses in vivo (see column 3 line 66 to column 4, line 28).

Whole viruses comprise nucleic acids encoding genes, and can be considered expression vectors. It is noted however that these compositions and methods do not require function of the viral nucleic acids for vaccine activity, rather this activity is dependent upon protein antigens in the viruses.

Thus either one of Allison or Wasmoen anticipates the claims.

***Summary***

Claims 1-4, 6-12, and 14-16 are rejected under the judicially created doctrine of obviousness-type double patenting.

Claims 1-4, 6-12, and 14-16 are rejected under 35 USC 112, first paragraph, as lacking enablement and written description.

Claims 1-4, 6-12, and 14-16 are rejected under 35 USC 112, second paragraph as indefinite.

Claims 1-4, and 9-12 are rejected under 35 USC 102 as anticipated.

6-8 14-17 FOA

***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

JEFFREY SIEW
PRIMARY EXAMINER
1/13/03